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MAR 2 0 1997

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,171,569 was filed on March 6, 1997, under 35 U.S.C. § 156. U.S. Patent No. 5,171,569 issued on December 15, 1992 from an application that claimed priority under 35 U.S.C. § 120 to an application that was filed on March 13, 1986. Accordingly, the original expiration date of the patent is December 15, 2009.

The assistance of your Office is requested in confirming that the product identified in the application, rFIX, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Applicant states that regulatory review occured under U.S. Public Health Service Act, 42 U.S.C. § 201 *et seq.* Furthermore, the description of the approved product is not clear from the application for patent term extension. It would be helpful if your Office would provide a copy of any parts of the IND or Biologics License Application which describe what rFIX is or how it is made. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: M.C. Meinert, Esq.
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